IN THE HIGH COURT OF JUDICATURE AT MADRAS

RESERVED ON : 22.10.2018

PRONOUNCED ON : 28.03.2019

CORAM

THE HONOURABLE Mr.JUSTICE P.RAJAMANICKAM

Crl.OP.No.10522 of 2013
and
M.P.No.1 of 2013

1. M/s.Abbott Healthcare Pvt Ltd.,
   Represented by its Director
   Mr.Thomas Freyman,
   Himachal Pradesh.

2. Mr.Thomas Freyman
   Director of M/s.Abbott
   Healthcare Pvt Ltd.
   Himachal Pradesh.

3. Mr.Rajesh Pandya
   Director of M/s.Abbott
   Healthcare Pvt Ltd,
   Himachal Pradesh.

4. Mr.Sudarshan Jain,
   Director of M/s.Abbott
   Healthcare Pvt Ltd.
   Himachal Pradesh.

5. Mr.Amal Keishikar,
   Director of M/s.Abbott
   Healthcare Pvt Ltd.
   Himachal Pradesh.

6. Mr.Anil Arora,
   Person responsible for conduct of
   M/s.Abbott Healthcare Pvt Ltd.
   Himachal Pradesh. ... Petitioners

Vs.

The Tamil Nadu State represented by
Drugs Inspector,
Cuddalore Range,
Office of the Drugs Inspector,
No.4, Arun Nagar, Sellankuppam,
Cuddaore-3. ... Respondent

PRAYER: Criminal Original Petition filed under Section 482 of Cr.P.C, praying to call for the records and quash the proceedings in STC.No.26 of 2013 pending on the file of the learned Judicial Magistrate No.2, Cuddalore.

For Petitioners : Mr.Kevik Setalvad, Senior Counsel
for M/s.RamasubramaniamAssociates

For Respondent : Mr.T.Shunmugarajeshwaran
Government Advocate (Crl.Side)

ORDER

This petition has been filed by the accused Nos.1 to 6 to quash the proceedings against them in S.T.C.No.26 of 2013 on the file of the Judicial Magistrate No.2, Cuddalore.

2. The facts leading to the filing of this petition are as follows:-

2(a) On 31.05.2011, the Drugs Inspector, Cuddalore Range, proceeded to the premises of M/s.Arcot Agencies, No.8, ALC Campus, Cuddalore and the impugned drug namely Phenesedyl new cough linctus was drawn for analysis. Intimation vide Form 17 No.22/11/SGB/CR dated 31.05.2011 for the sample drawn was given to M/s.Arcot Agencies, No.8, ALC Campus, Cuddalore, with acknowledgement. The above sample was sent for analysis under Form 18 to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai-6. It was reported as "Not of Standard Quality " by the Government Analyst (Drugs) vide report under Form 13 dated 28.08.2012 for the reason that " the sample does not confirm to label claim with respect to the content of Codeine Phosphate". After receiving copy of the analytical report, the respondent/complainant on 07.09.2012 issued a copy of analysis report in Form 13 and protocol of analysis as per Section 25(2) of the Drugs and Cosmetics Act, 1940 to M/s.Arcot Agencies, No.8, ALC Campus, Cuddalore, requesting them to disclose the name and address of the supplier of the impugned drug as per Section 18(A) of the Drugs and Cosmetics Act, 1940 and also requested to furnish the purchase, stock on hand and distribution particulars etc., of the impugned drug. The competent person, of M/s.Arcot Agencies, No.8, ALC Campus, Cuddalore, in reply letter dated 07.09.2012 had disclosed that

the impugned drug was acquired from M/s.Abbott Health Care Pvt Ltd, 120, Ground and 1st Floor, Kumaran Nagar, Seevaram 1st Street, Perungudi, Chennai-96.

2(b) On receipt of the said letter from M/s.Arcot Agencies, No.8, ALC Campus, Cuddalore, the respondent on 10.09.2012 sent a copy of the analytical report to M/s.Abbott Health Care Pvt Ltd, Perungudi, Chennai asking them to disclose the name of the person from whom, the impugned drug was purchased. The said Abbott Health Care Pvt Ltd., sent a reply letter dated 10.10.2012 in which, the authorized person had not signed. Further, the firm also not furnished the relevant details called for in the letter dated 10.09.2012. Hence, the respondent had sent another letter on 17.10.2012, calling for the particulars from whom, the impugned drug was purchased. One portion of sealed sample was also sent to the said firm as per Section 23(4) (iii) of the Drugs and Cosmetics Act,1940 so as to adduce evidence on the report of the Government Analyst. In the reply dated 26.10.2012, the firm had disclosed that the impugned drug was acquired from M/s.Abbott Health Care Private Ltd., Punjab. Hence, the respondent had sent a copy of the analytical report on 05.11.2012 to the said Company asking them to disclose the name and address of the persons from whom, the impugned drug was purchased. In the reply letter dated 28.11.12, the said firm had disclosed that the impugned drug was purchased from M/s.Abbott Health Care Private Ltd, Village Bhatauli Khurd, P.O.Baddi, District Solan, Himachal Pradesh, India. Hence, the respondent sent a show-cause memo dated 15.10.2012 to the aforesaid manufacturer, calling for the explanation for the contravention of Section 18(a) (i) of the Drugs and Cosmetics Act, 1940 for having manufactured for sale and sold a Not of standard quality drug. A copy of analytical report was also sent with the aforesaid show-cause memo. On 05.11.2012, the respondent had received the reply letter from the aforesaid company, wherein, the authorized signatory had stated that they had received the show cause memo. Further, the authorized signatory of the firm had stated that they are confident that the drug manufactured by them is of standard quality and further stated that they are not agreeing with the report of Government Analyst. Further, he has disclosed the persons responsible for conduct of the business and enclosed copy of the drug licenses and attested copy of memorandum and Article of association for the said Company. Hence, the respondent after getting sanction from the Director of Drugs Control Tamil Nadu, Chennai, filed a complaint against the aforesaid company and its Directors as they have contravened the provisions of Section 18 (a) (i) of the Drugs and Cosmetics Act, 1940, which is punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940.

3. Based on the aforesaid complaint, the learned Judicial Magistrate No.2, Cuddalore, has taken the case on file in S.T.C.No.26 of 2013 and issued summons to the accused persons. After receipt of the summons, the accused persons 1 to 6 filed the present petition under 482 of Cr.P.C to quash the proceedings against them in S.T.C.No.26 of 2013.

4.The respondent/complainant has opposed this petition by filing counter and additional counter.

5. Heard Mr.Kevik Setalvad, Senior Counsel for M/s.Ramasubramaniam Associates, the learned counsel for the petitioners and Mr.T.Shunmugarajeshwaran, learned Government Advocate (Crl.Side), for the respondent.

6. The learned counsel for the petitioners has submitted that the first company is diversified health care company involved in developing manufacturing and marketing pharmaceutical, diagnostic, nutritional and hospital products and its products being sold in 130 countries world wide. He further submitted that one of the products manufactured by the first petitioner company is Phensedyl Cough Syrup, a proprietary medicine. The said Phensedyl Cough Syrup is a combination drug, referred as FDC, which is formulation including two or more active Pharmaceutical Ingredient (API), DGHs approved formula of Phensedyl Cough Syrup contains the combinations of Chlorpheniramine Maleate (I.P.4mg) and Codeine Phosphate (I.P.10mg) in each 5 ml dose and is a proprietary medicine as defined under Section 3(h) (ii) of the Drugs and Cosmetics Act, 1940, (herein after referred to as the Act). He further submitted that the said Phensedyl Cough Syrup being a proprietary medicine which is not included in the edition of Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized by the Central Government. He further submitted that the Indian Pharmacopoeia is modelled over and historically follows the British Pharmacopoeia. He further submitted that the Government Analyst tested the same as per the British Pharmacopoeia (BP Method) for Codiene Phosphate and concluded that the same was not of standard quality for the reason that the sample does not confirm to label claim with respect to the content of Codeine Phosphate vide report dated 28.08.2012 i.e., after more than 15 months of taking the sample.

7. The learned senior counsel for the petitioners has further submitted that the sample being a FDC and not listed in any Pharmacopoeia, the BP method could not have been applied. BP method is applicable only in respect of single ingredient liquid formulation containing Codiene Phosphate, whereas, Phensedyl Cough Syrup is a combination of active ingredients of Chlorpheniramine Maleate and Codeine Phosphate. Hence, the

Government Analyst's report is erroneous. He further submitted that as per Rule 46 (4) of the Drugs and Cosmetics Rules, (herein after referred to as the Rules) that in case of non pharmacopoeial proprietary medicines, a test method given in books or journals, if followed shall be mentioned. The test method therefore followed must have been listed in a standard book or journal specific to the product being tested, but, in this case, the Government Analyst had acted in contravention of Rule 46(4) of the said rules. He further submitted that the Central Drugs Standards Control Organization has issued Guidelines to be adopted by the State Drug Control Organization for uniform implementation of the provisions of the Act and the Rules made thereunder. He further submitted that in Clause 9 of the said Guidelines it is stated that in the case of non-pharmacopeial or modified formulations, the samples may be tested as per procedure provided by the manufacturer and only in the case of non-receipt of such procedure, on request, the sample may be tested as per method of analysis available with the Government analyst, but in this case, no request was made to the petitioners to provide the procedures to be followed for testing the sample and hence, the Government Analyst's report cannot be accepted.

8. The learned senior counsel for the petitioners has further submitted that C and F Agent of the petitioner namely M/s. Abbott Health Care Pvt Ltd., Perungudi, Chennai 96 sent a scanned copy, show-cause notice to the petitioner No.1 and on receipt of the said show cause notice, the petitioner No.1 got its product Phensedyl tested by Pharaffiliates, an external Government approved Laboratory in respect of the control samples of the same batch and the said report clearly states that the contents of Chlorpheniramine Maleate and Codeine Phosphate were within the limits and met with the prescribed standards of quality . He further submitted that the C and F agent of the first petitioner had forwarded the reply of petitioners dated 28.09.2012 to the respondent on 12.10.2012, and also furnished all the information to the respondent as they sought for under show-cause notice dated 09.10.2012. The petitioners also sent reply to the show cause notice dated 15.10.2012. He further submitted that despite the fact that the respondent had received reply from the petitioners, the respondent had filed a complaint before the Judicial Magistrate No.2, Cuddalore on 30.01.2013 belatedly knowing fully well that the sample would expiry on February 2013. Thereafter, the petitioners received summons from the Court i.e., on 14.03.2013, the sample had already expired and therefore, the petitioners' opportunity to get the sample and thereby the petitioners are deprived of their valuable right of re-tested by the Central Drug Laboratory was lost. He further submitted that in the complaint, it is not averred that how the petitioners 2 to 6 are responsible for the day-to-day

administration of the company. He further submitted that the petitioners 2 to 6 cannot be prosecuted merely because they are the Directors of the Company and therefore he prayed to quash the proceedings against the petitioners herein.

9. The learned Senior counsel for the petitioners, in support of the aforesaid contentions, relied upon the following decisions:

(i) State of Maharashtra /vs/ Jawaharlal Shamlal Ujawane - 1979 Maharashtra Law Journal 50
(ii) State of Himachal Pradesh /vs/ Shri Nand Kishore and Others - MANU/HP/3208/2011 : 2012(1) Shim LC 252
(iii) Vishal Pharmaceuticals and Another /vs/ State of M.P - MANU/MP/0320/1998 : ILR[1999]MP704, 1999(2)MPLJ378
(iv) State /vs/ Hukam Chand, MANU/DE/8658/2007 : 2008(1)RCR(Criminal)97
(v) The State of Maharashtra /vs/ R.A.Chandawarkar and Others-MANU/MH/0435/1999:1999(5)BomCR519
(vi) State of Haryana /vs/ Brij Lal Mittal and Others -(1998) 5 Supreme Court Cases 343

10. Per contra, the learned Government Advocate (Crl.Side), who is appearing for the respondent/complainant has submitted that a portion of the sample which was manufactured by the first petitioner Company was sent to the Government Analyst, Chennai and the said Government Analyst gave a report stating that the said sample does not confirm to the label claimed with respect to the content of Codeine Phosphate IP. He further submitted that after issuing show-cause notice and receipt of reply from the petitioners and their agents, the respondent had made a request to the Judicial Magistrate No.2, Cuddalore to send the third portion of the Sample to the Central Government Drugs Laboratory, Kolkatta for test and accordingly, the said sample was sent to the Central Drugs Laboratory, Kolkatta and the Director of Central Drugs Laboratory, Kolkatta had sent a report on 01.04.2013 stating that a sample is not of standard quality as defined under the Cosmetics and Drugs Act, 1940 and the rules therein with respect to the content of Codeine Phosphate 49.65% (4.95 mg instead of 10 mg). He further submitted that as per Sub-Section 4 of Section 25 of the Act, the report received from the Director of Central Drugs Laboratory shall be conclusive evidence of the facts stated therein and hence after getting necessary sanction, the respondent has filed a complaint against the petitioners herein. He further submitted that the Government Analyst and the Director of Central Drugs Laboratory, Kolkatta have tested the samples in accordance with the rules and submitted reports stating that the Sample is not of standard quality and that being so, the report obtained by the petitioners from the private analyst cannot be accepted. He

further submitted that there are sufficient materials to proceed against the petitioners and hence he prayed to dismiss the petition.

11. The undisputed facts are as follows:

On 31.05.2011, the then Drugs Inspector of Cuddalore has drawn the sample of Phenesedyl New Cough Linctus. Chlorpheniramine Maleate and Codeine Phosphate Cough Linctus B.No.PHA1014, M/D:MAR-11, E/D: FEB 13. The said Drugs Inspector has sent the samples under Form 18 on 31.05.2011 to the Government Analyst for test. The Government Analyst has tested/analysed the said sample and sent a report in Form 13 dated 28.08.2012 stating that the sample was tested under BP method and the said sample contains Codeine Phosphate 6.39 mg (63.9%) whereas label claims 10mg and hence the said sample does not confirm the label claim with respect to the content of Codeine phosphate and it is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and rules thereunder. The said Drugs Inspector had issued show cause memo to the firm M/s.Arcot Agencies, No.8, ALC Campus, Cuddalore, from where he has drawn the sample and after getting the particulars about the manufacturers of the said drug, he issued show-cause memo to the petitioners herein who are the manufacturers of the said sample drug. The petitioners herein had sent a reply to the Drugs Inspector dated 28.09.2012 stating that the Government Analyst has not followed the guidelines issued by the Government of India, Ministry of Health and Family Welfare dated 26.11.2010. Thereafter, the respondent after getting necessary sanction from the competent authority has filed a complaint under Section 200 of Cr.P.C before the Judicial Magistrate No.II, Cuddalore.

12. According to the petitioners, the said Phenesedyl New Cough Linctus is a combination drug, referred as FDC, which is formulation including two or more active pharmaceutical ingredients and hence it is a proprietary medicine and it will not come in the edition of Indian Pharmacopoeia or any other Pharmacopoeia authorized by the Central Government. Their further case is that in respect of proprietary medicine, the Government of India, Ministry of Health and Family Welfare issued guidelines under Section 33 of the Drugs and Cosmetics Act, 1940 dated 26.11.2010, wherein it has been stated that the said medicine should be tested as per the procedure provided by the manufacturer , but, in this case, the Government Analyst has not made any request to provide the procedure being followed by the manufacturer.

13. For proper appreciation, the relevant clause of the said guidelines is extracted here under:

" The Patent and Proprietary formulations should be tested by the Government analysts as provided under rule 46 of the Drugs and Cosmetics Rules. In the case of non-pharmacopeial or modified formulations, the samples may be tested as per procedure provided by the manufacturer, which has been duly approved by the licensing authority. In case of non-receipt of such procedure on request the sample may be tested as per method of analysis available with the Government analyst".

14. The learned Senior counsel for the petitioners has submitted that in similar cases, the Government Analysts of other states have made requests to the first petitioner company to send the detailed method of analysis of the sample, but, in this case, the Government Analyst has not sent any such letter. He also produced xerox copies of the letters said to have been sent by the Government Analysts of other states viz Kolkatta, Delhi, Vadadora, Goa and Shillong.

15. Though the learned Senior counsel for the petitioners has produced copies of the letters said to have been sent by the Government Analysts of other states requesting the first petitioner to send the detailed method of analysis, he has not produced any proof to show that the first petitioner company has sent the detailed method of analysis to the respective Government Analysts. In this petition also, the petitioners have not enclosed their procedure for analysing the aforesaid proprietary medicine duly approved by the licensing authority. In this case, the respondent has filed an application before the Judicial Magistrate No.II, Cuddalore, requesting the Magistrate to send another sample which has been produced by him before the said Magistrate to the Central Drugs Laboratory, Kolkatta. Accordingly, the learned Judicial Magistrate No.II, Cuddalore along with the letter dated 07.02.2013 had sent another sample to the Central Drugs Laboratory, Kolkatta as per the provision of Section 25(4) of the Drugs and Cosmetics Act, 1940 for test/analysis. The Director of Central Drugs Laboratory, Kolkatta has sent a Certificate of Test/analysis dated 12.03.2013 in Form-2 stating that the sample contains codeine phosphate 4.965 mg whereas the label's claim is 10 mg and hence the sample does not confirm to label with respect to the content of 'codeine phosphate'. In the said certificate, it is also stated that the method of analysis applied with the reference the book: HPLC Quantitative Analysis of Pharmaceutical Formulations, Volume – 2, page No.411, Author. P.D.Sethi & Raja Sethi, First Edition: 2007.

16. At this juncture, it would be relevant to refer to Sub-Section 4 of Section 25 of the Drugs and Cosmetics Act, 1940

which reads thus:

> " Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the same of the drug [or cosmetic] produced before the Magistrate under sub-section (4) of the section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein."

17. A plain reading of the aforesaid provision would show that the report received from the Director of Central Drugs Laboratory shall be conclusive evidence of the facts stated therein. In this case, as already pointed out that the Director of Central Drugs Laboratory has sent a report in Form-2 dated 12.03.2013, wherein, it is stated that the sample contains Codeine Phosphate of 4.965 mg (49.65% of claim) whereas the claim made in the label is 10mg and hence the sample does not confirm to the claim with respect to assay i.e., content of codeine phosphate. Further, in the said report, it is stated that the testing method followed is HPLC (Ref: HPLC Quantitative Analysis of Pharmaceutical Formulations, Volume 2, Page No.411, Author : P.D.Sethi and Rajat Sethi, Edition, First Edition: 2007. So, it is clear that the Director of Central Drugs Laboratory has complied with the provision of Sub-Rule 4 of Rule 46 of the Drugs and Cosmetics Rules, 1945.

18. The learned senior counsel for the petitioners relying on the decision of the Hon'ble Supreme Court in Mohinder Singh Gill and Another /Vs/ The Chief Election Commissioner, New Delhi and Others, (1978) 1 SCC 403 contended that since in the report issued by the Government Analyst, the particulars as to the method analysis applied with reference to which book or journal has not been mentioned as contemplated under Sub-Rule 4 of Rule 46 of Drugs and Cosmetics Rule 1945, it cannot be supplemented by fresh reasons in the report given by the Director of Central Drugs Laboratory.

19. In the aforesaid decision, in Paragraph No.8 the Hon'ble Supreme Court has observed as follows:

" 8. The second equally relevant matter is that when a statutory functionary makes an order based on certain grounds, its validity must be judged by the reasons so mentioned and cannot be supplemented by fresh reasons in the shape of affidavit or otherwise. Otherwise, an order bad in the beginning may, by the time it comes to Court on account of a challenge, get validated by additional grounds later brought out. We may here draw attention to the observations of Bose, J in Gordhandas Bhanju:-

"Public Orders, publicly made, in exercise of a statutory authority cannot be construed in the light of explanations subsequently given by the officer making the order of what he meant or of what was in his mind, or what he intended to do. Public Orders made by public authorities are meant to have public effect and are intended to affect the actings and conduct of those to whom they are addressed and must be construed objectively with reference to the language used in the order itself."
Orders are not like old wine becoming better as they grow older".

20. As per Section 25(1) of the Drugs and cosmetics Act, 1940, the Government Analyst has to give his test or analysis report to the Inspector in triplicate in the prescribed form with regard to the sample of drugs received by him. As per Section 25 (3) of the Act, the report signed by the Government Analyst shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under Section 18-A has, within twenty eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report. In this case, the petitioners have not notified their intention of adducing evidence in controversion of the Government Analyst's report. Further, as per Section 25 (4) of the said Act, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug produced before the Magistrate under Section 23 (4) to be sent for test or analysis to the Central Drugs Laboratory and the report received from the Director of the Central Drugs Laboratory shall be conclusive evidence of the facts therein. Further, in this case, the Government Analyst has not given any explanation for non-mentioning of method of analysis applied with reference to which

book or journal. On the contrary, the Director of the Central Drugs Laboratory by exercising the power conferred under Section 25 (4) of the Act analysed another sample and gave his report and that will have over riding effect over the report of the Government Analyst. Therefore, the aforesaid decision will not apply to the facts of this case.

21. It is also to be pointed out that in this case, the petitioners instead of following the procedure prescribed under Sub section (3) of Section 25 of the Act, they have obtained a report from a private analyst and based on the said report, the petitioners contended that the sample satisfied with the claims made in the label. The said procedure is not prescribed under the law and therefore, the said report cannot be relied upon by the court.

22. As already pointed out that the petitioners have not produced their procedure with regard to testing of the sample. Further, they have not followed the procedure prescribed under sub-section (3) of Section 25 of the Act and that being so, they cannot make a complaint that the Government Analyst has not followed the guidelines issued by the Government of India.

23. The learned senior counsel for the petitioners has further submitted that the learned Judicial Magistrate No.2, Cuddalore had issued summons on 18.03.2013, but, even before that i.e., on February 2013 itself, the sample was expired and hence the petitioners have not made a request to the concerned Magistrate to send another sample to the Central Drugs Laboratory. He further submitted that the report sent by the Director of Central Drugs Laboratory also would show that analysis of the sample was done only on 12.03.2013 and the same would also show that the said analysis was done only after expiry period and therefore, no reliance can be placed upon the said report.

24. At this juncture, it would be relevant to refer to the decision in State of Haryana -Vs- Brij Lal Mittal and Others (1998) 5 SCC 343 wherein the Hon'ble Supreme Court in Paragraph Nos. 5 and 7 has observed as follows:

> 5. From a bare perusal of sub-section (3) it is manifest that the report of the Government Analyst shall be evidence of the facts stated therein and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address or other particulars have been disclosed under Section 18-A (in this case the manufacturers) has within 28

days of the receipt of the report notified in writing the Inspector or the court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report. Sub-section (4) also makes it abundantly clear that the right to get the sample tested by the Central Government Laboratory (so as to make its report override the report of the Analyst) through the court accrues to a person accused in the case only if he had earlier notified in accordance with sub-section (3) his intention of adducing evidence in controversion of the report of the Government Analyst. To put it differently, unless requirement of sub-section (3) is complied with by the person concerned he cannot avail of his right under sub-section (4).

7. At the risk of repetition, we wish to emphasis that the right to get the sample examined by the Central Drugs Laboratory through the court before which the prosecution is launched arises only after the person concerned notifies in writing the Inspector or the court concerned (here the latter clause did not apply for the prosecution was yet to be initiated) within twenty-eight days from the receipt of the copy of the report of the Government Analyst that he intends to adduce evidence in controversion of the report. The complaint and its accompaniments (which include correspondence that took place between the Inspector and the manufactures) clearly disclose that on 19.02.1991 the Inspector served the original copies of the Analyst's report upon the Managing Director of the manufactures along with two letters asking for their comments. They further disclose that receiving no reply from the manufactures the Inspector again wrote a letter on 06.03.1991 directing them to reply to his letters dated 19.02.1991 and asked whether they wanted to take benefit of the provisions of Section 25(3) of the Act. In spite thereof the manufactures did not exercise their right (much less within 28 days from the date of the receipt of the report of the Government Analyst, i.e., 19.02.1991); and, on the contrary, in their letter dated 08.04.1991 annexed the complaint), sent in response to the letter dated 06.03.1991, asserted that their Quality Control Department examined and tested samples of the two drugs and found that they complied with the test of sterility. It must,

> therefore, be said that consequent upon their failure to notify the Inspector that they intended to adduce evidence in controvention of the report within 28 days, not only the right of the manufactures to get the sample tested by the Central Drugs Laboratory through the court concerned stood extinguished but the report of the Government Analyst also became conclusive evidence under sub-section (3). The delay in filing the complaint till the expiry of the shelf-life of the drugs could not, therefore, have made a ground by the High Court to quash the prosecution. It will not be out of place to mention that the manufactures' right under sub-section (3) expired four months before the expiry of the shelf-life of the drugs. In view of the above discussion, the reasoning of the High Court for quashing the prosecution against the three respondents cannot at all be sustained.

25. As per Sub-section (3) of Section 25 of Act, the petitioners should have notified their intention of adducing evidence in controversion of the Government Analyst's report. If the petitioners notified their intention to adduce evidence in controversion of the Government Analyst's report, as per Sub Section (4) of Section 25 of the Act, the Court may sent the sample of the drugs produced before it for test or analysis to the Central Drugs Laboratory. Then it is for the Director of the Central Drugs Laboratory to say that since the sample has been sent after expiry period, the same was not fit for analysis, but, in this case, the petitioners have not notified their intention of adducing evidence in controversion of the Government Analysis report. On the contrary, at the request of the respondent /complainant, another sample was sent tot he Central Drugs Laboratory and after testing the said sample the Director of Central Drugs Laboratory gave a report as the sample does not confirm to the label claim. He has not stated that the sample was not fit for analysis. Therefore, the contention of the learned counsel for the petitioners that since the summons were issued only after expiry period of the sample, the petitioners have lost the right to send the sample for analysis to the Central Drugs Laboratory cannot be accepted.

26. In State of Maharashtra /vs/ Jawaharlal Shamlal Ujawane (cited supra), the Bombay High Court of Nagpur Bench has held that the provisions of Rule 46 of the Drugs and the Cosmetics Rules are mandatory and the Government Analyst is bound to furnish to the Drugs Inspector,the full protocols of the tests applied.

27. In Vishal Pharmaceuticals and Another /vs/ State of M.P (cited supra), the High court of Madhya Pradesh (Indoor Bench) also held that the Rule 46 is a mandatory provision and that should be followed strictly.

28. In State /vs/ Hukam Chand (cited supra), the High Court of Delhi has held that the Rule 46 is a mandatory provision and non-compliance of said rule by the Government analyst would show that the prosecution has not proved the charge against the accused beyond all reasonable doubt.

29. In The State of Maharashtra /vs/ R.A.Chandawarkar and Others (cited supra), the High Court of Bombay has held that the provisions of rule 46 of the Drugs and Cosmetics Rules are mandatory and that they must be fully complied with.

30. In this case, as already pointed out that a report from the Director of the Central Drugs Laboratory also has been received. In view of Sub- Section (4) of Section 25 of the Act, the report sent by the Director of the Central Drugs Laboratory will have over riding effect. In the said report, it is clearly stated the method of analysis followed by him by referring to a standard book viz., HPLC Quantitative Analysis of Pharmaceutical Formulations, Volume 2, Page No.411, Author : P.D.Sethi and Rajat Sethi, Edition, First Edition: 2007. So, it is clear that the Director of Central Drugs Laboratory has followed the mandatory provisions of Sub-Rule 4 of Rule 46. Therefore, the aforesaid decisions will not help the petitioners.

31. In State of Himachal Pradesh /vs/ Shri Nand Kishore and Others-(cited supra) the High Court at Shimla in Paragraph Nos.20 to 22 as follows:

> "20. A perusal of the complaint does not show that the aforesaid person(s) arrayed as the accused are the " Incharge of and' responsible to the company for the conduct of the business of the company' as contemplated in sub-section (1) of Section 34 ibid and the said person(s) must be a person/persons in over all control of the day to day control of business of the company or firm. If a partner of a firm, is not in such over all control, he cannot be liable to be convicted merely because he had a right to participate in the business of the firm under the terms of the partnership deed.
>
> 21. In the instant case, neither the partnership deed of the firm nor Memorandum of Association of the Company have been placed on record and in absence of the allegations, as aforesaid made

in the complaint even the oral testimony of the complainant/Drug Inspector cannot be relied upon.

22. It is thus seen that the vicarious liability of a person for being prosecuted for an offence committed under this Act by a company or firm arises if at the material time the person arrayed as the accused was "incharge of " and was responsible to the company for the conduct of its business. Simply because a person is Director of the Company, does not necessarily mean that the fulfils both the above requirement so as to make him liable. Conversely, without being a Director, a person can be incharge of and responsible to the company for the conduct of its business.

32. In State of Haryana /vs/ Brij Lal Mittal and Others in paragraph Nos.8 and 9 has held as follows:

" 8. Nonetheless, we find that the impugned judgment of the High Court has got to be upheld for an altogether different reason. Admittedly, the three respondents were being prosecuted as directors of the manufacturers with the aid of Section 34(1) of the Act which reads as Under:

34. Offences by companies-(1) where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in the Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence."

33. It is thus seen that the vicarious liability of a person for being prosecuted for an offence committed under the Act by a company arises if at the material time he was in charge of and was also responsible to the company for the conduct of its business. Simply because a person is a Director of the Company it does not necessarily mean that he fulfils both the above requirements so as to make him liable. Conversely, without being a director a person can be in charge of and responsible to

the company for the conduct of its business. From the complaint in question we, however, find that except a bald statement that the respondents were directors of the manufacturers, there is no other allegation to indicate, even prima facie, that they were in charge of the Company and also responsible to the Company for the conduct of its business.

34. In Municipal Corporation of Delhi Vs. Ram Kishan Rohtagi while dealing with the applicability of Section 17(1) of the Prevention of Food Adulteration Act, 1954, which is in pari materia with Section 34(1) of the Act, on similar facts, the Hon'ble Supreme Court observed as under : (SCC p.7, para 15)

> "15. So far as the Manager is concerned, we are satisfied that from the very nature of his duties it can be safely inferred that he would undoubtedly be vicariously liable for the offence; vicarious liability being an incident of an offence under the Act. So far as the Directors are concerned, there is not even a whisper nor a shred of evidence nor anything to show, apart from the presumption drawn by the complainant, that there is any act committed by the Directors from which a reasonable inference can be drawn that they could also be vicariously liable. In these circumstances, therefore we find ourselves in complete agreement with the argument of the High Court that no case against the Directors (Accused 4 to 7) has been made out ex facie on the allegations made in the complaint and the proceedings against them were rightly quashed. " (emphasis supplied)

35. From the aforesaid decisions, it is clear that the vicarious liability of a person for being prosecuted for an offence committed under the Act by a Company arises if at the material time he was in charge of and was also responsible to the company for the conduct of its business. It is also clear that simply because a person is a Director of the Company it does not necessarily mean that he fulfils both the above requirements so as to make him liable.

36. In this case, in the complaint filed by the second respondent, it is stated that the authorized signatory of the first petitioner had disclosed the persons responsible for the conduct of business and enclosed a copy of drugs licence, attested copy of memorandum and article of association for the first petitioner and based on the said particulars, the petitioners herein have been shown as accused. The petitioners have enclosed a copy of memorandum of association. In the memorandum of association, it is not stated that the petitioners

herein are incharge of and responsible for the company for the conduct of its business. In the complaint, except a bald statement that the petitioners 2 to 6 are Directors of the petitioner No.1, there is no other allegation to indicate even prima facie, that they were incharge of the Company and also responsible to the company for the conduct of its business. Therefore, in view of the aforesaid decision of the Hon'ble Supreme Court, merely because, the petitioners 2 to 6 are Directors of the first petitioner Company, they cannot be prosecuted for the offence said to have been committed by the first petitioner company and hence, this Court is inclined to allow the petition in so far as the petitioners 2 to 6 are concerned.

37. In so far as the first petitioner company is concerned, this Court is of the view that there are sufficient materials to proceed against it. According to the respondent/complainant, the sample is not of standard quality and hence, the said violation is punishable under Section 27(d) of the Drugs and Cosmetics Act, 1940. Under Section 27 (d) of the said Act, any drug other than the drug referred to clause (a) (b) or (c) in controvention of any other provision of the Chapter IV or any Rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees. As per the proviso to the said section, the court may for adequate and special reasons to be mentioned in the judgement, impose a sentence of imprisonment for a term less than one year.

38. At this juncture, it would be relevant to refer to the decision in Standard Chartered Bank and Others /vs/ Directorate of Enforcement and Others - 2005 Supreme Court Cases (Cri)961 wherein a constitution Bench of the Hon'ble Supreme Court in Paragraph Nos.31 and 32 has observed as follows:

> 31. As the company cannot be sentenced to imprisonment, the court cannot impose that punishment, but when imprisonment and fine is the prescribed punishment the court can impose the punishment of fine which could be enforced against the company. Such a discretion is to be read into the section so far as the juristic person is concerned. Of Course, the court cannot exercise the same discretion as regards a natural person. Then the Court would not be passing the sentence in accordance with law. As regards company, the Court can always impose a sentence of fine and the sentence of imprisonment can be ignored as it is impossible to be carried out in respect of a company. This appears to be the intention of the legislature and we find no difficulty in construing the statute in such a way. We

do not think that there is a blanket immunity for any company from any prosecution for serious offences merely because the prosecution would ultimately entail a sentence of mandatory imprisonment. The corporate bodies, such as a firm or company undertake a series of activities that affect the life, liberty and property of the citizens. Large -scale financial irregularities are done by various corporations. The corporate vehicle now occupies such a large portion of the industrial, commercial and sociological sectors that amenability of the corporation to a criminal law is essential to have a peaceful society with stable economy.

32. We hold that there is no immunity to the companies from prosecution merely because the prosecution is in respect of offences for which the punishment prescribed is mandatory imprisonment (sic and fine). We overrule the views expressed by the majority in Velliappa Textiles on this point and answer the reference accordingly. Various other contentions have been urged in all appeals, including this appeal, they be posted for hearing before an appropriate Bench.

39. From the aforesaid decision, it is clear that there is no immunity to the Companies from the prosecution merely because the prosecution is in respect of the offences for which the punishment prescribed is mandatory imprisonment. As regards company, the Court can always impose a sentence of fine and the sentence of imprisonment can be ignored as it is impossible to be carried out in respect of a Company. Therefore, merely because, Section 27 (d) prescribes mandatory punishment, there is no bar for prosecuting the first petitioner company.

40. For the aforesaid reasons, this petition is allowed in respect of the petitioners 2 to 6 and the proceedings against them in S.T.C.No.26 of 2013 on the file of the Judicial Magistrate No.2, Cuddalore, are quashed. In so far as the first petitioner Company is concerned, this petition is dismissed. It is open to the first petitioner, to contest the case before the Trial Court. The Trial Court is directed to dispose of the case against the first petitioner herein in accordance with law uninfluenced by the observations made by this Court in this Order. Consequently, connected miscellaneous petition is closed.

Sd/-
Assistant Registrar (CS-IV)

//True Copy//

vv

Sub Assistant Registrar

To

1. The Judicial Magistrate No.2,
   Cuddalore.

2. The Drugs Inspector,
   Cuddalore Range,
   Office of the Drugs Inspector,
   No.4, Arun Nagar, Sellankuppam,
   Cuddalore-3.

3. The Public Prosecutor,
   High Court, Madras.

+1 cc to M/s.S.Ramasubramanian & Associates, Advocate,
vide S.R.No.30042

Crl.OP.No.10522 of 2013
and
M.P.No.1 of 2013

CP(CO)
SSM(25/06/2019)